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(Article begins on next page)



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Osseous resective surgery with and without fibre retention technique in the treatment of shallow intrabony defects: a split-mouth randomized clinical trial.

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Running title:

FibReORS versus ORS in intrabony defects

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Abstract

Aim: The aim of this split-mouth clinical trial was to compare the effectiveness of Apically Positioned Flap with Fibre Retention Osseous Resective Surgery (FibReORS) or Osseous Resective Surgery (ORS) in the treatment of periodontal pockets associated with intrabony defects ≤ 3 mm at posterior natural teeth.

Materials and Methods: Twenty-six posterior sextants requiring osseous resective surgery were selected in 13 chronic periodontitis patients: 13 sextants were randomly assigned to ORS and 13 to FibReORS. Clinical evaluation of probing depth (PD), gingival recession and clinical attachment level was performed at baseline, 6 and 12 months postoperatively. Periapical radiographs were taken prior and after surgical treatment, at 6- and 12-month follow-up.

Results: Ostectomy amounted to 1.0 ± 0.3 mm in the ORS group and to 0.4 ± 0.2 mm in the FibReORS group. At 12-month examination PD changes did not significantly differ between the experimental groups. ORS group showed significantly ($p < 0.001$) greater clinical attachment loss (2.2 ± 1.0 mm *versus* 1.0 ± 0.6 mm), radiographic bone resorption (0.43 ± 0.08 mm *versus* 0.13 ± 0.09 mm) and post-operative patient discomfort compared to FibReORS.

Conclusion: FibReORS resulted in similar PD reduction, but less ostectomy, clinical attachment loss and patient morbidity compared to ORS.

Clinical relevance

Scientific rationale for the study: Limited information is available on the effectiveness of Fibre Retention Osseous Resective Surgery (FibReORS) compared with Osseous Resective Surgery (ORS) in the treatment of periodontal pockets associated with an intrabony component ≤ 3 mm at posterior sextants.

Principal findings: At 1-year follow-up the FibReORS-treated defects showed similar PD reduction but significantly less bone resorption, apical displacement of the gingival margin and dental hypersensitivity than the ORS-treated sites.

Practical implications: FibReORS represents an attractive alternative to ORS in the treatment of shallow-moderate intrabony defects at posterior natural teeth.

Introduction

After non surgical treatment, residual periodontal pockets more than 4 mm deep, especially when associated with persisting bleeding on probing, may represent a site-specific positive predictive factor for further clinical attachment loss during supportive periodontal therapy (Claffey et al. 1990, Claffey & Egelberg 1995, Matuliene et al. 2008). Several long-term studies documented that, in presence of residual pockets, the surgical treatment performs better than the non-surgical therapy alone in terms of incidence of periodontal disease progression (Kaldahl et al. 1996, Serino et al. 2001). Therefore, the treatment of residual pockets may be recommended (Matuliene et al. 2010).

In shallow intrabony defects, where regenerative therapy is usually not indicated, among surgical treatment options osseous resective therapy (ORS) with Apically Positioned Flap (Ochsenbein 1958) results in higher periodontal pocket reduction and lower incidence of disease progression in the long term period compared with conservative surgery (Becker et al. 1988, Kaldahl et al. 1996).

The endpoints of ORS are to achieve minimal probing depths (PDs), to recreate positive bone and gingival tissue contours and to obtain adequate width of keratinized tissue by means of proper hard and soft tissue management (Carnevale & Kaldahl 2000).

The Fibre Retention Osseous Resective Surgery (FibReORS) was proposed to reduce the amount of supporting bone removed (Carnevale 2007). This treatment modality is based on the histological findings by Gargiulo et al. (1961) that supracrestal periodontal fibers inserted in the root cementum are always present for approximately 1-2 mm coronally to the bottom of the defect. Therefore, the aim is to recontour the bone crest by considering not only the mineralized tissue but also the supracrestal connective tissue attachment when applying the principles of the osseous resective surgery. The level of the connective tissue fibers inserted in the root cementum becomes one of the reference points to determine the amount of bone removed, leading to a more conservative bone resection (Carnevale 2007, Carnevale et al. 2008).

Previous retrospective studies (Carnevale et al. 2007a,b) observed that patients treated with FibReORS experienced minimal tooth loss and recurrence of periodontal pockets during a mean follow-up period of 8 years (range 3-17 years).

Limited data from randomized controlled clinical trials is available on the effectiveness of FibReORS compared to ORS (Cairo et al. 2013). Therefore, the aim of the present study was to compare the clinical and radiographic effectiveness of these surgical approaches in the treatment of shallow intrabony defects (≤ 3 mm) at posterior natural teeth with a split-mouth design.

Material and Methods

Experimental design

This article is reported according to the CONSORT statement to improve the quality reporting of randomized controlled clinical trials. This was a single-centre, prospective, double-blinded, split-mouth randomized clinical trial designed to evaluate the clinical and radiographic outcomes 12 months following two different surgical treatments of shallow intrabony defects: Apically Positioned Flap plus FibReORS (test) versus Apically Positioned Flap plus ORS (control). Each patient provided two contralateral posterior sextants which were randomly assigned to the test or control procedure.

The patients were consecutively selected among individuals undergoing non-surgical periodontal treatment at the Section of Periodontology, C.I.R. Dental School, Department of Surgical Sciences, University of Turin, in the period comprised between June and December 2011. The study protocol, in full accordance with the ethical principles of the Declaration of Helsinki of 1975 as revisited in 2000, was approved by the local Ethical Committee. Patients gave written informed consent to participate in the study.

All participants had to meet all the following inclusion criteria: 1) age ≥ 18 years; 2) chronic periodontitis (Armitage 1999); 3) systemically healthy; 3) non-smokers; 4) full-mouth plaque score (FMPS) and full-mouth bleeding score (FMBS) $\leq 15\%$; 5) aetiological periodontal therapy (motivation and instructions to perform oral hygiene procedures, full-mouth scaling and root

planing) terminated at least 3 months prior to screening; 6) presence of two contralateral posterior sextants with natural teeth containing at least one defect with residual PD \geq 5 mm, persisting bleeding on probing (BoP), and an associated intrabony component \leq 3 mm as detected on radiographs.

Exclusion criteria were as follows: 1) aggressive periodontitis; 2) contraindications for periodontal surgery; 3) pregnancy and lactation; and 4) the following periodontal conditions in the treatment sextants: previous periodontal surgery; prosthetic restorations or natural teeth with undetectable cemento-enamel junction (CEJ); horizontal bone loss higher than 1/3 of the root length; severe furcation involvement (degree II or III, Hamp et al. 1975); and severe mobility (degree II or III, Miller 1950).

Sample size

The difference in clinical attachment level (CAL) between test and control procedures was set as the primary outcome. Determination of the required sample size was based on a previous study (Cairo et al. 2013). A sample size of 11 patients was estimated to detect a clinically relevant difference for CAL of 0.5 mm with 80% power (standard deviation = 0.5 and two-sided alpha error = 0.05). To compensate for possible drop-outs 13 patients were recruited, for a total of 13 sextants to be treated with each surgical technique. After verification of the entry criteria, patients were enrolled consecutively until the minimum number was reached.

Randomization and blinding

Patients were randomized after enrolment, with the test or control treatment assigned to the right or left sides. The treatment side as well as the treatment sequence (first treatment FibReORS or ORS) were randomly assigned using computer-generated randomization tables with patients numbered according to the order in which they were consecutively enrolled. To conceal allocation, the corresponding forms were put into opaque envelopes with the patient number on the outside. The sealed envelopes were placed into the custody of a clinician who was not involved in diagnosis or treatment delivery. After the patient entered in the surgical room he opened the first envelope and

informed the surgeon which was the first sextant to be treated. After the defects were degranulated, he opened the second envelope and informed the surgeon which randomly assigned surgical treatment was to be performed.

Randomization was implemented by a person not involved in the study. The examiner who performed the measurements was different from the clinician who provided the surgical treatment and was not involved in the supportive periodontal care. Patients did not receive information about the type of surgical procedure that was used in each sextant.

Data collection

Clinical measurements

The following clinical parameters were assessed in the treated sextants at baseline (1 week before surgery), 6 and 12 months after the surgical procedure using the same type of periodontal probe (PCP 15/11.5, Hu-Friedy, Chicago, IL, USA): 1) presence/absence of plaque at 6 sites/tooth (PI), 2) presence/absence of BoP at 6 sites/tooth, 3) PD measured as the distance in mm from the free gingival margin (GM) to the base of the pocket/sulcus at 6 sites/tooth, 4) gingival recession (Rec) measured as the distance in mm between GM and CEJ at 6 sites/tooth, 5) CAL measured in mm from the CEJ to the apical point of the pocket/sulcus at 6 sites/tooth, and 6) tooth mobility (degree 0, I, II, III, Miller 1950). The percentages of total surfaces which revealed plaque or BoP within each subject were expressed as FMPS and FMBS.

In addition, at baseline, immediately after the surgical session, and 12 months postsurgery the apico-coronal dimension of the keratinized tissue (KT) was recorded as the distance in mm from the GM to the mucogingival junction (MGJ) at the mid-buccal aspect of the treated sites.

All measurements were taken by the same calibrated investigator (GMM) who was masked to the treatment. For the calibration exercise five chronic periodontitis patients not enrolled in the study were evaluated by the designated examiner on two separate occasions, 24 h apart. Calibration was accepted if measurements of full-mouth PD and CAL at baseline and at 24 h were similar to the millimeter at $\geq 90\%$. The agreement was between 91% and 94%.

Radiographic measurements

The radiographic examination was performed at baseline (prior to the surgical session), 10 days (suture removal), 6 and 12 months after surgery. One week before the surgical session, an alginate impression was taken to fabricate a template in autopolymerized acrylic resin. Four 1-mm diameter metal balls were inserted and fixed with self-curing resin in the template at the level of teeth to be treated. Preoperative and postoperative radiographs were taken with the long-cone paralleling technique and digital phosphor sensor (Digora ® model Optime 2009 Soredex) using the template.

After having minimized size distortions with a dedicated software, linear measurements were performed by a blinded and calibrated engineer (CB) from the Polytechnic of Turin with the Image J software, a program of digital image processing, based on Sun-Java, developed by the National Institute of Health in the United States. It has a plugin editor and a Java compiler that make it possible to process and analyse the images. The radiographic reference points were the CEJ, the bone crest level (BC), the bottom of the bony defect (BD), where the ligament space was considered having a normal width (Schei et al. 1959, Bjorn et al. 1969). Referring to the above mentioned points the CEJ-BC and the BC-DB were measured at the interproximal sites of all the treated teeth in the sextant.

Evaluation of post-operative morbidity

Patients were asked upon completion of the surgery to report about intraoperative pain and personal feeling of the hardship of the procedures. A horizontal visual analogue scale (VAS), 10-cm long, was used to score the intensity (0=no pain/hardship; 10=extreme pain/hardship). Patients were also asked at week 1, 2 and 4 to quantify postoperative pain intensity on a VAS.

Surgical procedures

All surgeries were performed by the same clinician (MA) with more than 15 years of experience in periodontal surgery using loops 5X under coaxial light. The test and control sextants were treated on the same surgical session. The test group received the Apically Positioned Flap plus FibReORS (Carnevale et al. 2007), whereas the control group the Apically Positioned Flap plus ORS

(Ochsenbein 1958).

Antibiotic (amoxicillin 1g) and anti-inflammatory therapy (ibuprofen 600 mg) was administered 1 h prior to the surgery. Intra-oral antisepsis was performed with 0.2% chlorhexidine digluconate (CHX) rinse for 2 min before starting the surgical procedure. Following administration of local anesthesia with articain (2%) and epinephrine (1:100,000), at the buccal side internally bevelled paramarginal or intrasulcular incisions were made based on PD values and on the apico-coronal dimensions of KT. A split-thickness flap beyond the MGJ was then raised. Vertical releasing incisions were used to improve access as far as deemed necessary. At the lingual side, internally bevelled incisions were positioned at paramarginal or intra-sulcular level, consistent with the amount of PD and KT, and a split-full-thickness flap was reflected. The elevation of the flap was kept at minimum to allow the exposure of the defect. At the palatal area the thinned palatal flap technique was performed.

Bone remodelling was carefully made by using manual and rotary instruments in order to reshape positive attached fibres/bony architecture. Great attention was made in the differential diagnosis between inflammatory tissue and connective fibres connected to the root cementum by means of a periodontal probe. The soft tissue not attached to the root surface was gently removed by using a microsurgical blade. The root surfaces were carefully scaled and planed to completely remove subgingival calculus.

Before and immediately after bone remodeling the following measurements were made on 6 sites per tooth by a clinician not involved in the surgical treatment (EE):

- CEJ - BC₀: distance between CEJ and BC before bone remodelling
- BC₀ – BD: distance between BC and BD before bone remodelling
- CEJ - BC₁: distance between CEJ and BC after bone remodelling
- BC₁ – BD: distance between BC and BD after bone remodelling

The flaps were firmly sutured at the bone crest level.

Post-surgical instructions

Patients were prescribed amoxicillin 1g and ibuprofen 600 mg to be taken every 12 h for 5 days. They were advised to avoid toothbrushing and flossing in the treated area and to rinse three times a day for 1 min with a 0.12% chlorhexidine gluconate solution for 2 weeks after surgery. Sutures were removed after 10 days. After 2 weeks patients resumed oral hygiene procedures with a soft toothbrush. They were monitored at 7, 10, 14 and 28 days during which gentle supragingival professional tooth cleaning was performed. After 1 month postsurgery, patients received individualized oral hygiene instructions consistent with the modified gingival contours and resumed normal hygiene practices with medium toothbrush and interdental devices. Thereafter, they were enrolled into a 3-month maintenance programme.

Statistical analysis

Data were analysed with patients as the unit of statistical assessment. Clinical and radiographic parameters of all sites involved in the surgical procedure were measured at baseline and at follow-up examinations, and the mean value of each parameter was calculated for each patient and time interval. The experimental site, selected as the deepest intrabony defect in the sextant at the time of presurgery recordings, was used for further comparison and statistical analysis of clinical variables. Primary outcome variable was the average change in CAL from baseline to 12 months and secondary outcome variables were PD, Rec, and CEJ-BD.

Descriptive statistics were performed using mean \pm standard deviation (SD) for quantitative variables and frequencies and percentage for qualitative variables.

Data collected at baseline in the two treatment groups were compared using the Student's *t*-test for paired samples for parameters with normal distribution (PD, CAL, radiographic parameters), the Wilcoxon test for those with non Gaussian distribution (FMPS, FMBS, VAS scores). Within-group comparisons of the changes in clinical and radiological parameters from baseline to 12 months were analysed using repeated-measurement analysis of variance or the Friedman's test. Multiple comparisons were conducted with post-hoc tests (Newman-Keuls test and Dunn test).

Subsequently, pairwise comparisons between the groups were performed using the paired *t* test and Wilcoxon test. The Bonferroni correction was used to confirm any significant values arising from multiple comparisons. Data analyses were performed using a commercially available statistical software package (SAS 9.2). The experimental level of significance (α) was set as 0.05.

Results

The flowchart of the experimental design is presented in Fig. 1. A total of 25 subjects were assessed for their eligibility; 10 did not meet the inclusion criteria, while the other 2 refused to participate for working reason. Finally, 13 subjects (3 males, 10 females, mean age 48.4 ± 4.7 years) were enrolled in the study. Thirteen sextants (6 maxillary and 7 mandibular) were treated with FibReORS, while 13 with ORS (7 maxillary and 6 mandibular). Surgical procedures were performed between January and October 2012. All 12-month follow-up visits were completed in November 2013. No subject discontinued participation in the study and no data points were missing for analysis.

Clinical outcomes

Table 1 summarizes clinical parameters at baseline, 6 and 12 months after surgery. At baseline, no statistically significant differences ($p > 0.05$) were observed between test and control sextants.

No post-surgical healing complications occurred in both the experimental groups. A slight/moderate oedema in the surgical area was recorded in 7 (53.8%) of the FibReORS-treated sextants and in 11 (84.61%) of the control ones at week 1. Interproximal fibrin deposits were a frequent occurrence in the control group. They were detected at week 1 in 9 (69.23%) of the ORS-treated sextants while they were visible in only 2 (15.39%) FibReORS-treated sextants. At week 2 the test sextants were fully sealed, whereas control sites displayed complete wound healing at week 4.

During the 12-month period patients maintained FMPS and FMBS values $<15\%$, showing a good level of plaque control. Both surgical techniques resulted in statistically significant overall changes in PD, Rec and CAL between baseline and 12-month examination ($p < 0.001$), whereas KT was nearly unchanged. As shown in Table 1, the greatest PD reduction and CAL loss occurred during the first 6 months postsurgery ($p < 0.0001$), whereas no further significant changes were observed

within the treatment groups between 6 and 12 months ($p > 0.05$).

In the FibReORS-treated sextants the intrasurgical depth of the intrabony component assessed as BC₀-BD was on average 1.0 ± 0.3 mm and the ostectomy amounted to 0.4 ± 0.2 mm. The BC₁-BD after remodeling was 0.5 ± 0.4 mm.

CAL values increased from 3.8 ± 1.0 mm to 4.8 ± 0.8 mm during the 12-month period ($p < 0.001$). An overall PD decrease of 1.5 ± 0.5 mm and a REC increase of 2.5 ± 1.0 mm were observed at 12 months ($p < 0.0001$). A coronal displacement in the gingival margin position of about 1.8 ± 0.7 mm was detected between the end of the FibReORS procedure and the 12-month follow-up.

In the ORS-treated sextants the mean BC₀-BD was 1.1 ± 0.3 mm and the bone resected amounted to 1.0 ± 0.3 mm. The BC₁-BD was 0.04 ± 0.1 mm.

CAL values increased on average from 3.7 ± 0.8 mm to 6.1 ± 1.0 mm ($p < 0.0001$). During the experimental period PD values decreased on average by 1.1 ± 0.6 mm and Rec increased by 3.5 ± 1.1 mm ($p < 0.0001$). Gingival tissues experienced a coronal regrowth of about 1.2 ± 0.8 mm during 12 months after surgery.

Similar results were obtained when analyzing data from experimental sites. In the test group the BC₀-BD was 1.7 ± 0.8 mm and the amount of ostectomy was 0.5 ± 0.7 mm. The BC₁-BD amounted to 1.1 ± 0.7 mm. After 12 months the mean PD reduction and the mean Rec increase amounted to 3.0 ± 1.2 mm and 3.1 ± 1.1 mm, respectively.

In the control group the depth of the intrabony defect was 2.1 ± 0.6 mm and 0.2 ± 0.4 mm before and after remodelling, respectively. The ostectomy amounted to 1.9 ± 0.8 mm. The ORS procedure resulted in mean PD reduction of 2.6 ± 0.5 mm and mean Rec increase of 4.8 ± 0.9 mm at 12-month evaluation.

Changes in clinical parameters over the 12-month period were significantly different between the two surgical procedures at both sextant and experimental site level ($p < 0.001$). The test group showed less ostectomy and apical displacement of the gingival margin, lower CAL loss but comparable PD reduction and KT changes.

Radiographic outcomes

Radiographic data are summarized in Table 2. There were statistically significant differences between test and control sextants in the amount of ostectomy and in bone resorption ($p < 0.001$), whereas a similar reduction in the BC-BD values between baseline and 12-month follow-up was observed ($p > 0.05$). At 12 months the final BC-BD was 0.2 ± 0.2 mm and 0.1 ± 0.2 mm at test and control sextants, respectively. The ostectomy, calculated as the difference between the CEJ-BC values recorded at baseline and at 10 days, was respectively 0.38 ± 0.09 mm in the FibReORS-treated sextants and 0.92 ± 0.11 in the ORS-treated sextants. The extent of bone resorption at 12 months, calculated as the difference between the CEJ-BC values recorded at 10 days and 12 months, was 0.13 ± 0.09 mm for the FibReORS and 0.43 ± 0.08 mm for the ORS procedure.

Patient-centered outcomes

None of the patients reported intraoperative pain or personal feeling of hardship of the procedures at the end of the surgery (Table 3). When analysing the early healing phase, patients experienced significantly greater pain in the ORS-treated sextants compared with the FibReORS-treated sites during the first two postoperative weeks ($p < 0.001$). At week 4 pain was no longer reported.

Discussion

Although previous studies demonstrated positive outcomes after ORS (Olsen et al. 1985, Becker et al. 1988, 2001, Kaldhal et al. 1988, Kaldhal et al. 1996b) or FibReORS treatment (Carnevale et al. 2007a,b, 2008), to the best of our knowledge only one randomized controlled investigation with a parallel design compared the 12-month performance of osseous resective surgery with and without fibre retention technique during the treatment of shallow-moderate periodontal intrabony defects (Cairo et al. 2013). Thus, this randomized split-mouth trial was conducted to compare ORS and FibReORS for the treatment of intrabony defects at posterior natural teeth.

All the enrolled patients were non-smokers, displayed good performance in home plaque control (FMPS $< 15\%$) and presented with two posterior sextants with intrabony defects ≤ 3 mm. The

present results demonstrated that, independent of the surgical procedure, minimal probing depths were achieved and maintained over a 12-month period.

A pivotal aspect to take into account is the quantity of supporting bone needed to be removed in order to obtain complete defect elimination and to surgically correct reversed osseous topography. Clinical studies dealing with ORS reported an average amount of removed supporting bone following ostectomy ranging from 0.06 mm to 1.2 mm (Carnevale & Kaldhal 2000). In the present investigation, control sextants had a mean ostectomy of about 1.0 mm, while the mean bone resection at test sextants was minimal (0.4 mm), leading to a statistically and clinically significant difference between groups ($p < 0.001$). At the experimental site, which corresponded to the baseline deepest intrabony defect in the selected sextant, the difference between test and control procedures was more than threefold (0.5 mm *versus* 1.9 mm). Taking in mind this difference in bony resection at sextant (0.6 ± 0.2 mm) and experimental site level (1.4 ± 1.0 mm), the FibReORS yielded a consistent preservation of supporting bone.

The present findings are consistent with those by Cairo et al. (2013) who reported a mean height of marginal bone removed of 1.8 mm and 0.4 mm at control and test sites, respectively.

The less extent of bone removal in the FibReORS group is attributable to the preservation of the supracrestal connective fibres attached to the root cementum. The biological basis of the FibReORS approach is founded on histological studies demonstrating that supra-alveolar connective tissue has approximately the same height in periodontally healthy (1.07 mm) and diseased sites (1.06 mm) (Gargiulo et al. 1961, Vacek et al. 1994). Therefore, the coronal part of the connective tissue fibre attachment is considered as the bottom of the defect and the supporting bone resection is performed accordingly (Carnevale 2007). In contrast, the ostectomy performed according to the traditional ORS technique shifts the bottom of the intrabony defect to the most coronal part of the new interdental bone surface to recreate a positive bone architecture (Ochsenbein 1958).

Another aspect to take into account is the amount of bone remodelling during the wound-healing process following osseous surgery. An additional mean radiographic vertical bone loss of 0.43 mm

due to postsurgical remodelling was observed in the sextants treated with ORS at 12-month examination. At the same time point sextants treated by FibReORS displayed an average height of crestal bone loss of 0.13 mm and the difference between the surgical procedures was statistically significant ($p < 0.001$). Few studies are available in the literature on the amount of bone remodelling after ORS. They observed a mean bone resorption between 0.2 mm and 1.0 mm at 4-6 months after the elevation of a full-thickness flap and bone reshaping (Donnenfeld et al. 1970, Moghaddas & Stahl 1980). Data on crestal bone loss after FibReORS procedure are reported only in the study by Cairo et al. (2013). They observed a radiographic mean difference of about 1 mm between test and control sites at 12-month follow-up. However, radiographic measurements were taken before the osseous surgery and 12 months later. Interestingly, in the study by Moghaddas & Stahl (1980) no correlation could be established between the quantity of bone resected and the amount of bone lost after 6 months of healing. Thus, it is likely that the preservation of the supracrestal connective fibres attachment plays a key role in limiting crestal bone remodeling that is necessary to provide a space for the supracrestal connective attachment while restoring the physiological biological width. Previous experimental studies demonstrated that the preservation of attached fibres prevents the apical down-growth of the epithelium, the bone resorption and the connective attachment loss (Levine & Stahl 1972, Carnevale et al. 1983).

Concerning soft tissue behaviour, postsurgical gingival recession was greater in the control group compared to the test group at sextant (5.0 mm *versus* 4.5 mm) and experimental site level (7.9 mm *versus* 7.0 mm), but differences did not reach statistical significance. A different behaviour between surgical procedures was observed over the 12-month healing period. At the sextant level, a coronal regrowth of the gingival tissues of about 1.8 mm was detected following the FibReORS technique compared to a mean coronal displacement of 1.2 mm in the ORS group. When analysing data on the experimental site level, a coronal displacement of the gingival margin position of approximately 3.3 and 2.7 mm was detected in the test and control groups, respectively ($p < 0.001$). These findings

might be explained by the greater clinical attachment loss observed in the control group compared to the test one.

The present data are different from those reported by Cairo et al. (2013), who observed a more severe postsurgical recession at ORS-treated sites (5.8 mm) compared to FibReORS sites (4.2 mm), but a similar coronal soft tissue migration after surgery (2.2 mm *versus* 2.3 mm, respectively). The greater postsurgical recession observed in the present study might be attributed to the greater supracrestal component of the periodontal defects.

With regards to patient intraoperative comfort, no difference was detected between the two surgical procedures in the patient perception. No one reported any negative feeling during surgery. In this study the surgical chair-time was not recorded. It is important to point out that the operating time is influenced by the number of defects involved in the surgery and by the complexity of the anatomy. Furthermore, it should be underlined that the intra-surgical clinical and photographic documentation is time demanding. Thus, the chair-time may be different in non-experimental settings.

Regarding postsurgical morbidity, patients experienced more intensive pain in the control sextants during the first two postoperative weeks. Although the early healing period was uneventful in all the cases, interestingly soft tissue healing was slower in the ORS-treated sites. A complete epithelialization was observed at the 4-week follow-up visit, while test sites experienced complete wound healing at the 2-week examination. This favourable healing process agrees well with the promising clinical and patient-centered outcomes and may be due to the protecting effect of the preserved supracrestal connective tissue.

Along with the greater amount of resected bone, the most intense post-operative pain might be related to an exacerbated inflammatory response following the ORS procedure. An increased IL-1 β expression was observed one week after ORS surgery with rotary instruments compared to piezoelectric devices (Graziano et al. 2012).

The limitation of the present trial was the small sample size, but a split-mouth design was applied and the results were consistent with those available in the literature.

An aspect to be addressed is that only non-smokers with a high compliance with home care procedures were enrolled in the present trial. In addition, all surgical interventions were performed by an experienced clinician. FibReORS should be regarded as technique sensitive. It requires a careful root debridement to eliminate the not-attached connective tissue and to identify the coronal level of attached fibres. This step is very delicate especially at posterior natural teeth. These findings may limit the external generalizability of the present findings.

In conclusion, the FibReORS procedure was more effective in limiting the intrasurgical osteotomy, the apical displacement of gingival margin and the amount of bone remodelling than ORS over a 12-month period and was associated to negligible morbidity and suitable patients satisfaction.

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Table 1. Mean values of clinical parameters at baseline, 6 and 12 months postsurgery.

	<i>FibReORS</i> (n=13)		<i>ORS</i> (n=13)		<i>Differences between FibReORS and ORS</i>
	<i>Sextant</i>	<i>Experimental site</i>	<i>Sextant</i>	<i>Experimental site</i>	
<i>PD (mm)</i>					
<i>Baseline</i>	3.6 ± 0.6*	5.9 ± 1.2*	3.4 ± 0.6*	5.5 ± 0.7*	NS [‡]
<i>6 months</i>	2.2 ± 0.3**	2.7 ± 0.5**	2.1 ± 0.3**	2.5 ± 0.5**	NS [§]
<i>12 months</i>	2.1 ± 0.4**	2.9 ± 0.4**	2.3 ± 0.5**	2.9 ± 0.6**	NS [§]
<i>Rec (mm)</i>					
<i>Baseline</i>	0.2 ± 0.5*	0.6 ± 0.8*	0.3 ± 0.5*	0.4 ± 0.7*	NS [‡]
<i>Post-surgery</i>	4.5 ± 1.0**	7.0 ± 1.3**	5.0 ± 1.2*	7.9 ± 1.2**	NS [§]
<i>6 months</i>	2.9 ± 0.8**	4.0 ± 1.0**	3.9 ± 0.9**	5.3 ± 1.0**	<0.001 [§]
<i>12 months</i>	2.7 ± 0.7**	3.7 ± 1.1**	3.8 ± 1.0**	5.2 ± 1.0**	<0.001 [§]
<i>CAL (mm)</i>					
<i>Baseline</i>	3.8 ± 1.0*	6.5 ± 1.2 [†]	3.7 ± 0.8*	5.9 ± 0.9*	NS [‡]
<i>6 months</i>	5.1 ± 0.9**	6.7 ± 1.1	6.0 ± 0.8**	7.8 ± 1.0**	<0.001 [§]
<i>12 months</i>	4.8 ± 0.8**	6.6 ± 1.0	6.1 ± 1.0**	8.1 ± 1.1**	<0.001 [§]
<i>KT (mm)</i>					
<i>Baseline</i>		3.3 ± 0.5 [†]		3.4 ± 0.6 [†]	NS [‡]
<i>Post-surgery</i>		2.7 ± 0.4		2.6 ± 0.5	NS [§]
<i>12 months</i>		3.3 ± 0.5		3.5 ± 0.5	NS [§]
<i>Ostectomy (mm)</i>	0.4 ± 0.2	0.5 ± 0.7	1.0 ± 0.3	1.9 ± 0.8	<0.0001 [‡]
<i>BC₀-BD (mm)</i>	1.0 ± 0.3 [#]	1.7 ± 0.8 [#]	1.1 ± 0.3 [#]	2.1 ± 0.6 [#]	NS [‡]
<i>BC_I-BD (mm)</i>	0.5 ± 0.4	1.1 ± 0.7	0.04 ± 0.1	0.2 ± 0.4	<0.0001 [‡]

Experimental site, the baseline deepest intrabony defect in the treated sextant; CAL, clinical attachment level; KT, keratinized tissue; PD, probing depth; Rec, gingival recession; NS, difference between groups is not statistically significant (p>0.05); *p<0.001, p-values represent changes among the three time points (ANOVA); **p<0.0001, p-values represent longitudinal changes from baseline (Newman-Keuls test); [†]p>0.05, p-values represent changes among the three times points (ANOVA); [#]p<0.001, p-values represent changes among the two time points (paired *t*-test); [‡] paired *t*-test; [§]Bonferroni-corrected paired *t*-test; Data are reported as mean ± SD.

Table 2. Radiographic parameters

	FibReORS (n=13)	ORS (n=13)	P-value FibReORS vs ORS
Ostectomy (mm)	0.38 ± 0.09	0.92 ± 0.11	<0.001†
Bone resorption (mm)			
6 months	0.08 ± 0.10*§	0.46 ± 0.10*§	<0.001§
12 months	0.13 ± 0.09	0.43 ± 0.08	<0.001§

*p> 0.05, p-values represent changes between 6 and 12-month examination; §Bonferroni-corrected paired *t*-test; †paired *t*-test; Data are reported as mean ± SD.

Table 3. Patient experience in terms of intra- and post-operative pain (VAS units)

	FibReORS		ORS		P-value FibReORS vs ORS
	N (%)	VAS score	N (%)	VAS score	
During surgery	0 (0)	0	0 (0)	0	NA
Week 1	12 (92.3)	3.2 ± 1.9	13 (100)	6.8 ± 2.3	<0.001*
Week 2	7 (53.8)	1.2 ± 1.4	12 (92.3)	3.9 ± 2.1	<0.001*
Week 4	0 (0)	0 (0)	0 (0)	0	NA

VAS units, visual analogue scale units (with 0=no pain and 10=unbearable pain); * Wilcoxon test; NA, not applicable; Data are reported as mean ± SD.

Figure. 1 Consort diagram showing the study design

